IN THE UNITED STATES OF AMERICA
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Carmen Purl, M.D.; and Carmen Purl, M.D., PLLC d/b/a Dr. Purl's Fast Care Walk In Clinic, *Plaintiffs*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Office for Civil Rights of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*, and City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America, *Proposed Intervenor-Defendants.*	Civil Action No. 2:24-cv-00228

MEMORANDUM OF LAW OF PROPOSED INTERVENOR-DEFENDANTS IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

PRELIMINARY STATEMENT

Plaintiffs challenge rules that protect the confidentiality, use, and disclosure of patient health information involving lawful reproductive care. The confidentiality of patient health information that Plaintiffs seek to undermine is a cornerstone of effective health care and is governed by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936. Patients and clinicians alike rely on the protections afforded by HIPAA to use and disclose information regarding patient health care efficiently, effectively, and confidentially. HIPAA and its implementing regulations (the "Privacy Rules") ensure that identifiable patient information—including sensitive information touching on patients' symptoms, questions, fears, diagnoses, prognoses, test results, images, treatment, medical history, medication, wishes, and bills—is used and disclosed appropriately. When patient information does need to be disclosed for certain non-health care purposes, the Privacy Rules ensure that information remains confidential.

Plaintiffs target the final rule promulgated by the Department of Health and Human Services ("HHS" or the "Department") in 2024. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160, 164) (the "2024 Rule" or the "Rule"). The Department promulgated the 2024 Rule consistent with the statutory authority expressly delegated to it by Congress in HIPAA. Congress directed the Department to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information," including specifically as pertains to the "rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Proposed Intervenor-Defs.' Appx. to Br. in Supp. of Mot. for Summ. J., Dkt. No. 49-4 (hereinafter "Appx.") 561 (42 U.S.C. § 1320d-2 note) (codifying Pub. L.

104-191, title II, § 264)). Congress further directed the Department to "adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1). In promulgating the 2024 Rule, the Department considered the relevant factors and acted well within its discretion.

Plaintiffs (one individual physician and her private practice) now request an order vacating and permanently enjoining the 2024 Rule nationwide, asking this Court to prioritize their preferences over the clearly articulated will of Congress as represented by the text of the governing HIPAA statute. Plaintiffs cannot justify this extraordinary request.

Plaintiffs offer no meaningful argument that the 2024 Rule violates the Administrative Procedure Act. The 2024 Rule is entirely consistent with 42 U.S.C. § 1320d-7(b) and does not unlawfully limit disclosures regarding child abuse and public health reporting to state authorities. In arguing otherwise, Plaintiffs urge an interpretation of "limit" read entirely out of context and contrary to multiple canons of interpretation. Plaintiffs also fundamentally misapprehend the import of the 2024 Rule; under this rule, law enforcement continues to be able to access protected health information, *including* reproductive health care information, pursuant to the Privacy Rules' exceptions, as long as the disclosure is not sought for the prohibited purpose of imposing criminal, civil, or administrative investigation or liability on someone for merely seeking, obtaining, providing, or facilitating lawful reproductive health care.

The remainder of Plaintiffs' claims are equally invalid. The Department correctly defined the terms "person" and "public health," and Dr. Purl's personal beliefs about what constitutes child abuse and public health cannot be the source of the meaning of federal statutory and regulatory terms. And the administrative record conclusively demonstrates that the Department engaged in extensive, reasoned analysis and fully explained the 2024 Rule, including upon consideration of more than

25,900 comments representing 51,500 individuals and 250 organizations. Appx. 387 (89 Fed. Reg. 32991). Further, neither the major questions, non-delegation, nor vagueness doctrines provide any basis to invalidate the Rule (or the underlying statute). Moreover, universally vacating, enjoining, and setting aside the 2024 Rule nationwide, as these two related Plaintiffs demand, would be devastating for patients, providers, cities, and all who participate in the health care system. In seeking that relief, Plaintiffs contravene equitable principles and defy the Department's clear intention of severability.

ARGUMENT

I. THE 2024 RULE DOES NOT CONFLICT WITH THE PLAIN STATUTORY TEXT OF HIPAA

A. The 2024 Rule Does Not Unlawfully Limit Disclosures About Abuse and Public Health to State Authorities.

The 2024 Rule is fully consistent with the express terms of HIPAA. By its text, HIPAA and the regulations promulgated thereunder explicitly preempt contrary state law. 42 U.S.C. § 1320d-7(a)) ("[A] provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law . . . ."). This general preemption provision is subject only to limited exceptions, including:

> Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

Id. § 1320d-7(b).

As this Court has made clear, "[q]uestions of statutory interpretation begin and end, as they

must, with the text itself."[1] *Kelley v. Azar*, 2021 WL 4025804 at *10 (N.D. Tex. Feb. 25, 2021). Here, the contested terms—"invalidate or limit," "child abuse," and "public health surveillance, or public health investigation or intervention"—when given their plain meaning as originally intended by Congress, comfortably authorize the 2024 Rule, which narrowly impacts records involving the provision of legal reproductive care. Punishing lawful health care is not among the limited, statutory exceptions to HIPAA's general preemption provision. 42 U.S.C. § 1320d-7(b)). And Plaintiffs' attempt to portray the 2024 Rule as impacting one of the specific powers that *is* reserved for states requires defining key terms in a way that is at odds with the statute and mischaracterizing the practical application of the 2024 Rule itself.

(a) The Word "Limit" Must Be Understood in Its Context.

It is well-established that statutory analysis requires looking at words in their context—because "a word is known by the company it keeps." *Yates v. United States*, 574 U.S. 528, 543–44 (2015); *see also Sackett v. EPA*, 598 U.S. 651, 674–75 (2023) ("The meaning of a word 'may only become evident when placed in context.'") (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132, (2000); *Davis v. Mich. Dep't. of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.")); ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 195 (2012).

In drafting HIPAA, Congress stated that the general preemption provision does not "***invalidate or*** limit" certain other laws. 42 U.S.C. § 1320d-7(b)) (emphasis added). Applying the *noscitur a sociis* canon of construction, the word "limit" follows the word "invalidate," and therefore

[1] Plaintiffs' claim that "*Loper Bright* prevents HHS from receiving deference for its novel interpretation of HIPAA," Pls. Br. at 25, misses the mark. No deference is requested or required—the meaning is clear from the text of the statute.

must be understood with reference to its partner. Invalidate means that rules promulgated under HIPAA may not *literally* eliminate the "authority, power, or procedures established under any law" outlined in § 1320d-7(b). "Limit," then, is best understood to refer to *substantial impairment* of the same—in other words, HHS may not effectively eliminate one of the enumerated powers, even if it has not been literally invalidated.

Plaintiffs' arguments against the 2024 Rule rely substantially on imputing an extraordinarily broad meaning to the term "limit." Plaintiffs assert that a rule with *any impact* on the enumerated preemption exceptions, no matter how remote or incidental, represents an impermissible "limit" under HIPAA. But this construction violates no fewer than three core canons of statutory interpretation.

First, Plaintiffs rely exclusively on a dictionary definition of the word ("to curtail or reduce in…extent"). *Purl v. U.S. Dep't of Health & Hum. Servs.*, No. 2:24-cv-228, 2024 WL 5202497, at *8 (N.D. Tex. Dec. 22, 2024) (quoting *Limit,* MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2014)). But, as explained above, it is fundamental that statutory text must be construed as a whole—and here, the true meaning of limit "only become[s] evident when placed in context." *Sackett*, 598 U.S. at 674.

Second, under Plaintiffs' broad reading of "limit," any rule that "invalidate[s]" a preserved authority would necessarily also "limit" it—effectively reading the former term out of the statute in violation of the rule against surplusage, or "ascribing to one word a meaning so broad" that it assumes the same meaning as another statutory term.[2] *Fischer v. United States*, 603 U.S. 480, 487 (2024) (citing *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)). Courts are instructed to reject a

[2] The most reasonable reading avoids surplusage problems by reading "invalidate" as necessary to inform the scope of "limit," and, taken together, the terms provide that a rule can neither wholesale nullify or effectively nullify the listed powers.

statutory interpretation that would leave a term "with no work to perform" and should instead "seek to construe Congress's work so that effect is given to all provisions." *Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 686 (2022) (internal quotations omitted).

Third, Plaintiffs' broad construction would violate the presumption of consistent usage, under which a material variation in the use of a word or phrase suggests a variation in meaning. ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 195 (2012). While Section 1320d-7(b) refers to actions that "invalidate or limit," Section 1320d-7(c) uses "limit" alone—further supporting the idea that "invalidate" must have been used intentionally and in a way that modifies the term limit. Had Congress wanted to use the term limit on its own, they could have (and did).

Ultimately, context is key. And, read in context, "limit" must here impute some level of meaningful interference—or at least something more than even the barest of impacts, as Plaintiffs have argued.

(b) "Child Abuse" as Used in HIPAA Does Not Include Lawful Reproductive Care.

The 2024 Rule does not limit reporting of "child abuse" as that term is used in HIPAA. The 2024 Rule is a narrow prohibition of disclosure of a very specific class of protected health information ("PHI"): records of lawful reproductive care that are requested for the purpose of investigating or imposing liability on a patient or provider for the mere act of seeking or providing that care. 45 C.F.R. § 164.502(a)(5)(iii)(A). This narrow limitation on disclosure in no way impinges on the "procedures . . . for reporting . . . child abuse," and therefore is not contrary to the statute. 42 U.S.C. § 1320d-7(b)).

Put simply: lawful reproductive care is not "child abuse" within the meaning of HIPAA—regardless of whatever personal views Dr. Purl may hold. She claims that the 2024 Rule, despite its

narrow scope,[3] impermissibly "interfere[s] with [her] ability and legal obligation to disclose information about unborn children when they are victims of crime or abuse." Compl. at ¶ 87. But HIPAA's preemption exception for reporting child abuse has *nothing to do* with the unborn.

First, Congress has explicitly defined the term "child"—across all federal laws—to mean someone "born alive." 1 U.S.C. § 8(a) ("In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words 'person', 'human being', 'child', and 'individual', shall include every infant member of the species homo sapiens who is born alive at any stage of development.").[4] That same statute goes on to specify that being "born alive" requires exiting a uterus. *Id.* § 8(b). This definition applies in every federal statute and every federal rule and regulation, including HIPAA and the 2024 Rule. *Id.* The same meaning of "child" applies when the word appears in the phrase "child abuse." Appx. 400 (89 Fed. Reg. 33004) ("the term 'child' in the Privacy Rule is consistent with th[e] definition [in 1 U.S.C. § 8]").

Second, "child abuse" as used in HIPAA cannot implicate legal abortion because, at the time Congress enacted HIPAA, abortion was a constitutionally protected right. Courts "interpret[] a statute in accord with the ordinary public meaning of its terms *at the time of its enactment."*

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[3] As discussed in *infra* Section I(A)(d) below, the 2024 Rule does not limit disclosure of child abuse where any indicia of abuse are present—other than the mere fact of receiving legal reproductive care.

[4] This section of the Dictionary Act also resolves Plaintiffs' contention that the 2024 Rule includes an impermissible definition of person, because the regulatory definition of person matches the definition mandated by Congress. 1 U.S.C. § 8(a); 45 C.F.R. § 160.103. The inclusion of an express definition of "person" among the Privacy Rule's defined terms (*see*, *e.g.*, 45 C.F.R. § 160.103 (defining 48 terms), § 164.501 (defining 14 terms)), properly matches the federal statutory definition. 1 U.S.C. § 8(a) (the definition of "child" and "person" applies in federal regulations); *see also Meese v. Keene*, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of the term excludes unstated meanings of that term.") (citation omitted).

Bostock v. Clayton Cnty., 590 U.S. 644, 654 (2020) (emphasis added); *see also Texas v. Biden*, 646 F. Supp. 3d 753, 767 (N.D. Tex. 2022) (Kacsmaryk, J.) (*citing New Prime Inc. v. Oliveira*, 586 U.S. 105, 113 (2019)). At the time HIPAA was enacted, lawful health care for pregnant people was not considered "child abuse," and that understanding of the term should not be judicially remodeled twenty years after the statute was enacted. *Bostock*, 590 U.S. at 654–55 ("If judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives.").

That Dr. Purl or even Texas law may define "person" differently has no bearing on the meaning of this term in a federal statute. *See Hopkins v. Cornerstone Am.*, 545 F.3d 338, 347 (5th Cir. 2008) (finding that federal and state labor laws may support different interpretations of "employee" and "independent contractor"); *see also Lambro v. United States*, 90 F.4th 1375 (Fed Cir. 2024) (stating that federal statutes and regulations provide specific definitions and standards that are authoritative for federal purposes). To hold otherwise—and allow states or individuals to supplant Congress's intentions with their own—violates core principles of federalism and runs roughshod over the explicit preemption provision in HIPAA. By analogy, another doctor may deeply hold a belief that another procedure—say, male circumcision—is abusive in any circumstances. Those views do not mean that circumcisions now fit within the statutory carveout that allows disclosure of PHI in reporting child abuse and for public health. That doctor is not entitled to report the protected health information relating to legal circumcisions as "abuse" simply because they have personally concluded that they would like to. It is the *original meaning* of the words that Congress used that matters. *See Hopkins*, 545 F.3d at 347; *Lambro*, 90 F.4th 1375; *see also United States v. Am. Trucking Ass'ns, Inc.*, 310 U.S. 534, 542 (1940) (holding that in interpreting statutes, courts

should construe the language as to give effect to the intent of Congress). And it is self-evident that in 1996, when Congress used the words "child abuse," those words did not include fetuses or lawful reproductive care.[5] *See* Appx. 400 (89 Fed. Reg. 33004) (identifying federal statutes that address child abuse reporting that were in place at the time HIPAA was enacted, and noting "[a]s used in these statutes, the term 'child abuse' does not include activities related to reproductive health care, such as abortion").

While Plaintiffs make general references to "gender transition," they fail to establish how the 2024 Rule's coverage of medical records regarding gender-affirming care in any way impedes state laws, including those governing the reporting of child abuse. Plaintiffs admit that they have *never* encountered a pediatric patient whose health care records include information about gender-affirming care, and do not assert that they have *ever* faced a subpoena or administrative request relating to this information. Pls.' Appx. 004, Dkt. No. 46. Nor do Plaintiffs establish any connection between the Texas law on "gender transition procedures," Pls. Br. at 22,—which regulates *health care providers'* provision of certain treatments—to abuse reporting requirements. In short, even if Plaintiffs' entirely speculative encounter with a minor patient who has received gender-affirming care should come to pass, Plaintiffs have not pointed to any law establishing that doctors who encounter such a minor patient must report that patient as "abused" simply for having received legal gender-affirming care.

(c) The Plain Meaning of the Word "Public Health" Indicates That It Relates to Population-Level Health Information.

"Public health" is a well-established term of art used to describe *population-level* efforts to

[5] The Rule "[does] not. . . . disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities," and providers continue to be "permitted to make such disclosure [of reproductive care records] where there is suspicion of sexual abuse that could be the basis of permitted reporting." Appx. 400 (89 Fed. Reg. 33004).

study and promote health—and that is precisely how it is used in HIPAA. The 2024 Rule defines[6] "public health" as "population-level activities to prevent disease in and promote the health of populations"; it is *not* investigation or imposition of liability on specific individuals for the mere act of seeking or providing legal health care. 45 C.F.R. § 160.103. That is consistent with the inclusion of "public health surveillance, or public health investigation or intervention" as exceptions to preemption in the HIPAA statute. 42 U.S.C. § 1320d-7(b).

This is a simple textual analysis. The dictionary definition of public health is: "the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science." *Public Health,* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed., 2014). Definitions of the term from medical and legal dictionaries, the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry, and many states are in accord with this definition: public health information is that which affects the health of communities while disclosures of individual health information merely to punish that individual for the care is not a public health disclosure. Appx. 397 (89 Fed. Reg. 33001 nn. 233–34 (citing "Health, Public Health," BLACK'S LAW DICTIONARY (11th ed. 2019) and "Public Health," STEDMAN'S MEDICAL DICTIONARY 394520)).

Plaintiffs, however, seek to use the "public health" preemption exception in Section 1320d-7 as an open license to disclose confidential health records about specific persons in connection with lawfully obtained reproductive health care. They argue that "disclosure of information to investigate or prosecute violations of a state's abortion laws" qualifies as "'public health' reporting protected by § 1320d-7(b)." Pls.' Br. in Supp. of Mot. Summ. J., Dkt. No. 45 (hereinafter "Pls. Br.") at 26–27;

[6] To be clear, the HIPAA statute empowers the Secretary of HSS to "adopt modifications to the standards [promulgated under HIPAA] (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1); 45 C.F.R. § 160.103.

see also id. at 29 ("The 2024 Rule will unlawfully limit [abortion] reporting procedures."). But § 1320d-7(b) does not protect public health "*reporting*"—it refers specifically to "public health *surveillance*, or public health *investigation* or *intervention.*" (emphasis added). *See also* Appx. 400 (89 Fed. Reg. 33004) ("A covered entity may continue to use or disclose PHI for all the public health activities and purposes listed in section [1320d-7(b)]"). The Court should not read words into the statute that are not there. ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 107 (2012); *see also Lindh v. Murphy*, 521 U.S. 320, 330 (1997).

Alternatively, contrary to the plain words of the statute and their plain meaning, Plaintiffs advocate for an even more general "public health" exception, suggesting the 2024 Rule "usurp[s] the prerogative of states to protect public health using their traditional police power." Pls. Br. at 27. But, as discussed, HIPAA contains a general express preemption provision with respect to regulation of health records, subject to limited and specific exceptions. *See infra* Section II(B). Plaintiffs expansive view of state primacy in the public health sphere, translated into a broad construction of the term "public health" in § 1320d-7(b), would make for an exception that swallows the Rule. Nearly any "authority, power, or procedure" could be characterized as relating to "public health," thereby subverting the HIPAA preemption provision entirely.

(d) Plaintiffs Fundamentally Misconstrue the Narrow Scope of the 2024 Rule.

The 2024 Rule is narrow in scope and effect—it sets new standards governing requests for information about *lawful* reproductive health care for the *purposes of investigating or imposing liability* on a person for the *mere act* of seeking or providing the care. 45 C.F.R. 164.502(a)(5)(iii)(A) (emphasis added). Under any reasonable reading of the HIPAA statute—and even under Plaintiffs' most expansive (but incorrect) reading—the 2024 Rule does not run afoul of any of the enumerated powers reserved to the states in the statute's exceptions to preemption. 42 U.S.C. § 1320d-7(b). To

the contrary, the Rule "*does not seek* to prohibit disclosures of PHI where the request is for reasons *other than* investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating [lawful] reproductive health care." Appx. 390 (89 Fed. Reg. 32994) (emphasis added). And Plaintiffs mischaracterize the practical impacts of the 2024 Rule, painting it as much broader than it actually is.

The 2024 Rule does not prevent the lawful reporting of child abuse, as Plaintiffs claim, because a provider who suspects abuse based on their contacts with a patient, including their reproductive health care contacts, may continue to report that suspicion. *See* Appx. 400 (89 Fed. Reg. 33004) ("the regulated entity is permitted to make such disclosure [reporting suspected child abuse] where there is suspicion of sexual abuse that could be the basis of permitted reporting"). Nor does the 2024 Rule curtail disclosures related to public health efforts. Population-level public health efforts are "distinguished" from activities punishing individuals for the legal health care they seek or provide—with the 2024 Rule intentionally leaving intact state powers over the former. Appx. 397 (89 Fed. Reg. 33001); *see also* 45 C.F.R. § 160.103. Again, the 2024 Rule only prevents disclosure of records regarding lawful health care, when the purpose of the request is to investigate or prosecute an individual on the sole basis of having obtained or provided that lawful care.

II. THE 2024 RULE IS CONSISTENT WITH HIPAA'S LAWFUL DELEGATION OF AUTHORITY TO HHS

A. The 2024 Rule Is Consistent with HIPAA's Express Delegation of Authority to the Department.

HHS promulgated the 2024 Rule pursuant to an express grant of authority from Congress. Congress, through HIPAA, directed HHS to promulgate standards with respect to the privacy of individually identifiable health information. Congress provided detailed guidance in the statute about what these standards should do: improve "the efficiency and effectiveness of the health care

system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note). And to fulfill this directive, Congress directed the HHS Secretary to recommend privacy standards that addressed "[t]he rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d-2 note). Congress also set itself a deadline. If it failed to act on the Secretary's recommendations and enact legislation within three years, it empowered the Secretary to "promulgate final regulations containing such standards." *Id.* Of importance here, Congress "contemplated that [HHS's] rulemaking would not be static," and "specifically built in a mechanism to adapt such regulations as technology and health care evolve." Appx. 377 (89 Fed. Reg. 32981). To this end, Congress directed "the Secretary [to] review the standards adopted . . . and [to] adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1).

That is precisely what HHS did in promulgating the 2024 Rule. As directed by Congress, the Secretary adopted modifications that he determined were appropriate in light of the "changing legal landscape."[7] Appx. 374 (89 Fed. Reg. 32978). The Secretary explained in detail that in the aftermath

[7] The 2024 Rule is merely the latest in a history of lawful updates to the baseline HIPAA privacy rules, adopted in accordance with HIPAA's mandate that HHS "promulgate," "review," and "adopt modifications," to the rules. Appx. 561 (42 U.S.C. § 1320d-2 note); 42 U.S.C. § 1320d-3. As here, modifications to the HIPAA privacy rule have historically been made in accordance with changes to the health law landscape. For example, in 2009, the Breach Notification Rule was added to the privacy rules in response to passage of the HITECH Act. 74 Fed. Reg. 42740 (Aug. 24, 2009). In 2013, the Omnibus Rule modified the Privacy Rule to strengthen protection of genetic information in response to the Genetic Information Non-Discrimination Act. 78 Fed. Reg. 5566 (Jan. 25, 2013). In 2014, the Privacy Rule was modified in response to the Clinical Laboratory Improvement Amendments (CLIA) regulations. 79 Fed. Reg. 7290 (Feb. 6, 2014).

of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), "the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect" had increased, because the threat of disclosure for purposes of conducting an investigation or imposing liability "is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers . . . . " Appx. 374 (89 Fed. Reg. 32978). This, in turn, threatens the "efficiency and effectiveness of the health care system," Appx 549 (42 U.S.C. § 1320d note), that HIPAA endeavors to protect and without which individuals' ability to continue obtaining lawful health care services is impaired. Appx. 374 (89 Fed. Reg. 32978).

Plaintiffs contend that in promulgating the Rule, HHS acted in contravention of the authority Congress delegated to it under HIPAA. Pls. Br. at 29. To the extent that argument recycles the argument that the 2024 Rule places an unlawful "limit" on Dr. Purl's reporting to state authorities, the previous section demonstrates why that argument fails. To the extent Plaintiffs are making a separate "delegation of authority" argument, that argument fails because the Rule is consistent with Congress's express delegation of authority and because the Department has always been clear as to how covered entities should continue to make permissible disclosures in response to law enforcement requests. *See*, *e.g.*, Appx. 405–421 (89 Fed. Reg. 33009–25).

B. The 2024 Rule Is Consistent with General Principles of Federalism.

Although Plaintiffs argue that the 2024 Rule is contrary to federalism principles, it is Plaintiffs who seek to rewrite the balance between federal and state authority Congress established in 1996 with the passage of HIPAA. *See* Pls. Br. at 32.

And a 2016 Privacy Rule change allowed covered entities to disclose PHI to the National Instant Criminal Background Check System. 81 Fed. Reg. 382 (Jan. 6, 2016).

HIPAA *expressly preempts* contrary state laws. 42 U.S.C. § 1320d-7(a); *see supra* Section I.A. All that is required of Congress is a plain statement that makes its "intention 'clear and manifest'" to "pre-empt the historic powers of the States." *See Will v. Mich. Dep't. of State Police*, 491 U.S. 58, 65 (1989) (citation omitted). HIPAA clearly does so. 42 U.S.C. § 1320d-7(a)—which specifies that any "provision or requirement" or "standard or implementation specification adopted or established" under the Rule "shall supersede any contrary provisions of State law"—not only provides clear notice of Congress's intention to preempt state law but also includes explicit and limited exceptions to federal preemption. As described above, the 2024 Rule does nothing to disturb the longstanding balance between state investigative authorities and the privacy concerns animating HIPAA and only clarifies that obtaining legal reproductive health care is in and of itself not a basis for disclosure of records. *Id.* § 1320d-7(b); *see also supra* Section I.A.(c).

Plaintiffs' reliance on *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991), to invoke the states' "substantial sovereign powers," Pls. Br. at 32, fares no better. The 2024 Rule does not regulate the provision of reproductive health care—it merely heeds Congress's directive to "adopt modifications" to the existing regulatory standards related to the privacy of medical records as it deems "appropriate." *See* 42 U.S.C. § 1320d-3(b)(1); *see also infra* Section II.C.(b).

C. None of the Issues Raised *Sua Sponte* by the Court Warrant Vacating the 2024 Rule.

(a) HHS Clearly Acted Within the Bounds of Congress's Delegation of Authority, as Set Forth Under *Loper Bright.*

Loper Bright Enterprises v. Raimondo sets forth a framework for how courts should assess questions of legal interpretation where a statute is silent or ambiguous. 603 U.S. 369, 412 (2024). And while the Court made clear that deference was not to be afforded to an agency's interpretation of such legal questions (that is left to the Court), Congress still had the ability to delegate authority to an agency. *Id.* at 395. "Where, as here, Congress has clearly delegated discretionary authority to

an agency," *Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 617 (5th Cir. 2024), the Court's duty is to "fix[] the boundaries of the delegated authority" and "ensur[e] the agency has engaged in 'reasoned decision making' within those boundaries." *Loper Bright*, 603 U.S. at 395 (2024) (citation omitted). *First*, HIPAA is facially clear and unambiguous in delegating to HHS the responsibility of promulgating standards regarding the privacy of individuals' health information, which it did by promulgating the 2024 Rule. Appx. 561 (42 U.S.C. § 1320d-2 note); *see also Loper Bright*, 603 U.S. at 394–95 (stating that a statute may authorize an agency to exercise discretion by "empower[ing] an agency to prescribe rules to fill up the details of a statutory scheme") (citation omitted). *Second*, HHS indisputably engaged in reasoned decision-making when promulgating the 2024 Rule. *See infra* Section III.

(b) The 2024 Rule Does Not Trigger a "Major Question."

The 2024 Rule regulates only the disclosure of health care records pursuant to powers the agency has had for decades, since HIPAA's 1996 mandate for the Secretary to promulgate rules that address the "uses and disclosures" of personal health information. Appx. 561 (42 U.S.C. § 1320d-2 note). It does not implicate the major questions doctrine.

The major questions doctrine applies, if at all, only when an agency "'claims the power to resolve a matter of great political significance' . . . 'seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities' . . . [or] 'seeks to intrude into an area that is the particular domain of state law.'" *Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 616 (5th Cir. 2024) (quoting *West Virginia v. EPA*, 597 U.S. 697, 743–44 (2022) (Gorsuch, J., concurring)). When evaluating whether an agency violates the major questions doctrine, courts must examine whether the agency derives its authority from "the vague language of an ancillary provision of the Act," *West Virginia*, 597 U.S. at 724 (citation omitted), or "whether the

agency has previously claimed the authority at issue." *Mayfield*, 117 F.4th at 617; *see also West Virginia*, 597 U.S. at 725. An agency action is more likely to violate the major questions doctrine when it effectuates "'a fundamental revision of the statute, changing it from [one sort of scheme] of . . . regulation' into an entirely different kind," *West Virginia*, 597 U.S. at 728 (citation omitted), or when the "'agency has no comparative expertise' in making certain policy judgments." *Id.* at 729 (citation omitted); *see also King v. Burwell*, 576 U.S. 473, 474 (2015) ("It is especially unlikely that Congress would have delegated this decision to the IRS, which has no expertise in crafting health insurance policy of this sort."). None of these circumstances apply here.

First, the agency did not "exercise power of vast . . . political significance," *Alabama Ass'n of Realtors v. U.S. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021) (internal quotations omitted), nor does the 2024 Rule seek to "resolve a matter of great political significance." *Mayfield*, 117 F.4th at 616. The 2024 Rule merely reinforces the privacy protections regarding the disclosure of health care records for lawful care. *See*, *e.g.*, 45 C.F.R. § 164.502(a)(5)(iii)(B) (prohibiting disclosure when the "reproductive health care is lawful *under the law of the state* in which such health care is provided," or "protected, required, or authorized by Federal law") (emphasis added). This limited action is consistent with HHS's well-established authority under HIPAA because it only regulates how health care records are handled *after* care has been sought—not whether that care should be sought in the first instance. *See*, *e.g.*, *id.* § 160.103 (stating that the reproductive health care definition "shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care"); *id.* § 164.502 (regulating "uses and disclosures of protected health information"); *see also* Proposed Intervenor-Defs.' Br. in Supp. of Mot. Summ. J., Dkt. No. 49-3 at 10.

Plaintiffs' contention that the major questions doctrine "forecloses the 2024 Rule's special

regime for 'reproductive health care,'" Pls. Br. at 30, rests upon an incorrect understanding of what the Rule regulates and when the major questions doctrine applies. The Rule does not "create special rules about abortion or gender transitions," or purport to legalize any other type of reproductive health care through HIPAA, as Plaintiffs maintain. *Id.* While Plaintiffs may certainly believe and argue in other forums that certain reproductive health care procedures should be prohibited, this is not the appropriate stance to take here. Plaintiffs' parsimonious interpretation of what the Rule does—in their words, "center[] on a type of procedure or condition, not on a type of record or information," Pls. Br. at 41—cannot subsume its actual purpose of regulating the uses and disclosures of PHI. The Rule does not wade into the national debate on abortion or gender identity politics, let alone create a "nationwide policy shift" about the legality, access, or regulation of reproductive health care, Pls. Br. at 30, and so does not implicate a matter of great political significance.

Second, the economic impact of the 2024 Rule bears no similarity to the "billions of dollars in spending" that have triggered the doctrine in other instances. *See*, *e.g.*, *Mayfield*, 117 F.4th at 616; *see also Biden v. Nebraska*, 143 S. Ct. 2355, 2372–73 (2023) (finding the major questions doctrine to be implicated when the government cancelled $430 billion in student loans, resulting in costs to the taxpayer estimated to be "between $469 billion and $519 billion"); *Alabama Ass'n of Realtors*, 594 U.S. at 764 (finding that the major questions doctrine applied to the COVID-19 eviction moratorium, the economic impact of which was estimated to be around "$50 billion"). Before enacting the Rule, HHS estimated that the total first-year costs attributable to it would amount to $595 million, which was inclusive of costs that were to be primarily borne by covered entities. Appx. 445 (89 Fed. Reg. 33049). These costs included: "(1) responding to requests for the use or disclosure of PHI for which an attestation is required; (2) revising business associate agreements; (3) updating the [Notice of Privacy Practices] and posting it online; (4) developing new or modified policies and

procedures; [and] (5) revising training programs for workforce members." *Id.* The estimate also included the associated costs of "requesting an exception from HIPAA's general preemption authority." *Id.* The Rule does not "substantially restructure" any market or have any impact on GDP at all. *West Virginia*, 597 U.S. at 715, 724 (noting that the Clean Power Plan was projected to "reduce GDP by at least a trillion 2009 dollars by 2040").

Finally, Plaintiffs do not contend (and nor could they) that the 2024 Rule "intrudes into an area that is the particular domain of state law," *Alabama Ass'n of Realtors*, 594 U.S. at 764, or that HHS has grounded its authority in "the vague language of an 'ancillary provision[]' of the Act," or "effected a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind." *West Virginia*, 597 U.S. at 724, 728 (citations omitted). This is for the same reason: the 2024 Rule's disclosure prohibition is an exercise of the Department's core authority under HIPAA to promulgate rules concerning permissible "uses and disclosures" of PHI, Appx. 561 (42 U.S.C. § 1320d-2 note), and to adopt appropriate modifications to those rules. 42 U.S.C. § 1320d-3(b)(1). It has done these things for decades. *See* Appx. 378 (89 Fed. Reg. 32982–83). Further, to the extent that Plaintiffs' objection that HIPAA does not mention "specific medical procedures," Pls. Br. at 30, is an argument that the 2024 Rule "fundamental[ly] revis[ed] . . . the statute," *West Virginia*, 597 U.S at 728, there is no "such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." *Bostock*, 590 U.S. at 669. It is in this same vein that "psychotherapy notes" are a particular type of medical record defined in the HIPAA Privacy Rule and subject to heightened disclosure requirements. 45 C.F.R. §§ 164.501, 164.508(a)(2). Finally, not only is HHS the agency with "comparative expertise in making certain policy judgments," *West Virginia*, 597 U.S. at 729 (internal quotations omitted), but is also the agency to which Congress *explicitly*

delegated rulemaking authority in the plain language of HIPAA. Appx. 561 (42 U.S.C. § 1320d-2 note). HHS acted well within its Congressional mandate.

(c) HIPAA Contains an Intelligible Principle to Guide HHS's Promulgation of the Rule.

Plaintiffs advance the argument that HIPAA provides no intelligible principle to guide HHS in promulgating the 2024 Rule, as is required under the non-delegation doctrine. Pls. Br. at 33–36. Specifically, Plaintiffs argue that HIPAA lacks specific guidance for how HHS should treat particular types of medical care, including reproductive health care, as well as how HHS should define "person," and "public health." Pls. Br. at 35–36. These arguments fail, as HIPAA's delegation of authority to HHS expresses a clear intelligible principle to guide the agency's rulemaking such that it is "well within the outer limits" of the non-delegation doctrine. *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 351–52 (4th Cir. 2003) (internal quotations omitted).

It is well-established that Congress can "delegate[] discretionary authority to an agency," including by "'expressly delegate[ing]' to an agency the authority to give meaning to a particular statutory term . . . empower[ing] an agency to prescribe rules to 'fill up the details' of a statutory scheme . . . or to regulate subject to the limits imposed by a term or phrase that 'leaves agencies with flexibility' . . . such as 'appropriate' or 'reasonable.'" *Loper Bright*, 603 U.S. at 394–395 (citation omitted). To delegate this discretionary authority, Congress must provide an "intelligible principle," but as the Fifth Circuit has explained, the "intelligible-principle test requires Congress to set out guidance that 'delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority.'" *Mayfield*, 117 F.4th at 620 (quoting *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989)). This standard is "'not demanding,'" and "the Supreme Court has only twice found an excessive delegation of power, doing so in each case because 'Congress had failed to articulate *any* policy or standard to confine discretion.'" *Id.* at 620–21 (emphasis in original)

(requiring only "*some*" guidance, even if not straightforward, clear, or uncontroversial) (quoting *Gundy v. United States*, 588 U.S. 128, 146 (2019)).

First, as Plaintiffs admit, their non-delegation argument is contradicted by *S.C. Med. Ass'n*, which identified "at least three sources within HIPAA that provide intelligible principles outlining and limiting the Congressional conferral of authority on HHS." 327 F.3d at 351. These track exactly the three requirements articulated in *Mayfield*, 117 F.4th at 620: (1) the mandate that the regulations address three specific topics, 42 U.S.C. § 1320d-2 note, (2) the preamble of the statute that sets forth the general purpose of HIPAA, *id.* § 1320d note, and (3) the limitations on "whom the Privacy Rule was to cover, *see* 42 U.S.C. § 1320d-1(a); what information was to be covered, *see* § 1320d(6) (defining "individually identifiable health information"); what types of transactions were to be covered, *see* § 1320d-2(a)(2); what penalties would accrue for violations of HIPAA, *see* §§ 1320d-5, 1320d-6; and what time lines and standards would govern compliance with HIPAA, *see* §§ 1320d-3, 1320d-4." *S.C. Med. Ass'n*, 327 F.3d at 351.

Second, Plaintiffs' reliance on *Securities and Exchange Commission v. Jarkesy*'s discussion of non-delegation in the securities fraud enforcement context is misplaced. 603 U.S. 109 (2024), *aff'g on other grounds*, 34 F.4th 446 (5th Cir. 2022). *First*, the Supreme Court never reached the non-delegation issue and instead affirmed on other grounds. *Id.* at 120–21 ("Since the answer to the jury trial question resolves this case, we do not reach the nondelegation . . . issue[]."). *Second*, the Fifth Circuit's *Jarkesy* ruling is inapposite. There, the court's ruling rested on the "total absence of guidance" provided to steer the SEC's "absolute discretion to decide whether to bring securities fraud enforcement actions within the agency instead of in an Article III court," neither of which are at issue here. *Jarkesy*, 34 F.4th at 462. Rather, in addition to the guidance identified in *S.C. Med. Ass'n*, 327 F.3d at 351, 42 U.S.C. § 1320d-7(b) *itself* constrains HHS's ability to limit the "reporting of disease

or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." *See Big Time Vapes, Inc. v. Food & Drug Admin.*, 963 F.3d 436, 445 (5th Cir. 2020) (non-delegation is satisfied when "Congress plainly limited the authority that it delegated"). Thus, HIPAA sets out exactly what the Supreme Court and the Fifth Circuit require for an intelligible principle: Congress articulated "the general policy," including in 42 U.S.C. § 1320d note, "the public agency which is to apply it," which HIPAA set out to be HHS in *id.* §§ 1320d-2 note, 1320d-3(b)(1), and "the boundaries of this delegated authority," including in *id.* § 1320d-7(b). *Mistretta*, 488 U.S. at 372–73; *see also Mayfield*, 117 F.4th at 621. In sum, Plaintiffs "ask for a level of specificity that the law does not . . . demand." *Mayfield*, 117 F.4th at 622.

(d) The Rule's Definition of Reproductive Health Care Is Not Void for Vagueness.

The 2024 Rule articulates definite and easily understandable prohibitions and, thus, is not void for vagueness. The void for vagueness doctrine requires "sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Gonzales v. Carhart*, 550 U.S. 124, 148–149 (2007) (citation omitted). Additionally, the Supreme Court has relied on scienter requirements as a way to "alleviate vagueness concerns," as they may "narrow the scope of the . . . prohibition and limit prosecutorial discretion." *Id.* at 149–50. In the Fifth Circuit, for a rule to be found void for vagueness in a facial challenge, plaintiffs must allege that the definition meets the high bar of being "impermissibly vague in all of its applications." *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023). Plaintiffs have not done so here. Pls. Br. at 36–37. While the Supreme Court has indicated a more lenient standard,[8] this still would not save Plaintiffs because they fail to assert *any* non-conclusory

[8] *See Johnson v. United States*, 576 U.S. 591, 595, 602 (2015) (holding that while a vague

allegations of vagueness. Pls. Br. at 36–37.

First, HIPAA's strict scienter requirement allays concerns regarding arbitrary and discriminatory enforcement. *Gonzales*, 550 U.S. at 148–150. According to Plaintiffs, that a violation of the Rule could trigger criminal penalties heightens concerns of Due Process violations. Pls. Br. at 37. However, HIPAA's criminal penalties provision includes a clear scienter requirement such that a violation of the Rule would only result in criminal penalties if the individual engaged in a *knowing* violation of the Rule. 42 U.S.C. § 1320d-6(a). Far from "heightening" Due Process concerns, Pls. Br. at 37, this scienter requirement "alleviate[s] vagueness concerns," *Gonzales*, 550 U.S. at 149–50.

Second, the 2024 Rule is clear on its face and offers detailed definitions and examples of the covered care. The Rule defines "reproductive health care" as a subset of the term "health care," which has long been defined by HHS. *See* 65 Fed. Reg. 82799 (Dec. 28, 2000) (defining "health care"); 45 U.S.C. § 160.103. Reproductive health care is even more precisely defined as health care "that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes." 45 U.S.C. § 160.103. A "non-exclusive list of examples that fit within the definition" provides even further clarity as to what types of records are covered under the Rule. Appx. 402 (89 Fed. Reg. 33005–06). Further, though Plaintiffs complain that "multiple layers of legal determinations . . . exacerbate this vagueness," Pls. Br. at 36, the Rule includes a presumption that reproductive health care is lawful, which "ensure[s] that the regulated entity is *not* required to make a determination about the lawfulness of such health care." Appx. 408 (89 Fed. Reg. 33012) (emphasis added); 45 U.S.C. § 164.502(a)(5)(iii)(C). The Department included multiple examples

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provision is not unconstitutional merely because some conduct clearly falls within the provision, the law may not "fail[] to give ordinary people fair notice of the conduct it punishes, or [be] so standardless that it invites arbitrary enforcement").

to "illustrate how the presumption would apply," when it would be overcome, and explained in detail how covered entities should comply with the attestation requirement. Appx. 425–28, 410–12 (89 Fed. Reg. 33029–32, 33014–16); *see also infra* Section III.

III. THE RULE IS NOT ARBITRARY AND CAPRICIOUS

The administrative record conclusively demonstrates that HHS engaged in extensive, reasoned analysis before promulgating the 2024 Rule. In asserting that the 2024 Rule is arbitrary and capricious, Plaintiffs fail to identify a single relevant factor that the Department did not consider. *See* Pls. Br. at 37–39; *Huawei Techs. USA, Inc. v. Fed. Commc'ns Comm'n*, 2 F.4th 421, 551 (5th Cir. 2021) (rejecting APA claim where "agency weighed the evidence differently than [plaintiff] and reached contrary but reasonable policy conclusions").

In conducting arbitrary and capricious review under the APA, the Court is to presume the agency's final action is valid and is to consider only whether that action "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *see also Barr v. Sec. & Exch. Comm'n*, 114 F.4th 441, 447 (5th Cir. 2024) ("Agency decisions are 'presumptively valid; the [petitioner] bears the burden of showing otherwise.'") (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep't of Health & Hum. Servs.*, 917 F.3d 837, 844 (5th Cir. 2019) (brackets in original)). The Court's review is "neither sweeping nor intrusive." *Fort Bend Cnty. v. U.S. Army Corps of Eng'rs*, 59 F.4th 180, 194 (5th Cir. 2023) (citing *Amin v. Mayorkas*, 24 F.4th 383, 393 (5th Cir. 2022)). The Court may not "substitute its judgment for that of the agency." *Overton Park*, 401 U.S. at 416.

The Department's explanation for adopting the Rule readily meets this "narrow and highly deferential" standard. *Huawei Techs.*, 2 F.4th at 456 (internal quotations omitted). After consulting with federal and state agencies and the National Committee on Vital and Health Statistics and

considering more than 25,900 comments representing 51,500 individuals and 250 organizations, the Department found that "th[e] changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system," and that the Rule's minimal alterations to the Privacy Rule would "provide[] peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." Appx. 374 (89 Fed. Reg. 32978); *see also* Appx. 372, 387 (89 Fed. Reg. 32976, 32991)); *Associated Builders & Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 228 (5th Cir. 2016) ("[A]n agency does not act in an arbitrary and capricious manner simply because it attempts to improve a regulatory scheme."). The Department also explained how the Rule is consistent with § 1320d-7(b) and clarifies that a covered entity may not "disclose PHI as part of a report of suspected child abuse based *solely* on the fact that a parent seeks reproductive health care (e.g., treatment for a sexually transmitted infection) for a child." Appx. 400 (89 Fed. Reg. 33004).

Plaintiffs' contrary arguments, Pls. Br. at 37–39, neglect the administrative record and are premised on an incorrect understanding of the Rule. The Department reasonably explained the Rule's requirements, including how covered entities determine the legality of reproductive health care when applying the 2024 Rule's disclosure prohibition. *See* Appx. 405–428 (89 Fed. Reg. 33009–32). "[W]here a request for PHI is made to the regulated entity that provided the relevant reproductive health care," that entity should review "all available relevant evidence bearing on whether reproductive health care was lawful under the circumstances in which it was provided." Appx. 411 (89 Fed. Reg. 33015). Plaintiffs presumably must already assess the legality of any services that they provide to their patients, and the Rule's provisions are no different. Conversely, the Rule recognizes that when a covered entity did not provide the reproductive health care at issue,

"it may not have access to all of the relevant information" to make a legal determination and is "*not* expected to conduct research or perform an analysis of an individual's PHI." Appx. 408 (89 Fed. Reg. 33012). The covered entity is also "*not* required to make a determination about the lawfulness of such health care." Appx. 411 (89 Fed. Reg. 33015). Instead, the entity can "presume[]" that the care is "lawful" unless it has "either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis the reproductive health care was not lawful." Appx. 410 (89 Fed. Reg. 33014); 45 C.F.R. § 164.502(a)(5)(iii)(C).

The Department also provided a detailed account of how covered entities can comply with the attestation requirement. *See* Appx. 425–28 (89 Fed. Reg. 33029–32). The Department explained that the attestation serves to alleviate "difficult[y] for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose" by requiring the relevant state or federal agency to provide certain forms of information to the covered entity when they seek information potentially related to reproductive health care, *see* Appx. 425–26 (89 Fed. Reg. 33029–30); described when covered entities are entitled to rely on the attestation and when further investigation would be warranted, *see* Appx. 427–28 (89 Fed. Reg. 33031–32); and provided a model attestation form and other resources to assist covered entities in applying the Rule, *see*, *e.g.*, *Model Attestation,* HHS (attached as Ex. A).

Plaintiffs' assertion, Pls. Br. at 39, that the Department provided "no explanation" for the Rule's framework is at odds with the record and ignores the scores of descriptions and examples of how covered entities can comply with the Rule's requirements. *See* Appx. 405–28 (89 Fed. Reg. 33009–32). The fact that the 2024 Rule required covered entities to determine whether governmental requests for information are valid is "consistent with the current and longstanding practice under the Privacy Rule" where covered entities are responsible for determining the applicability of the Privacy

Rule's permitted disclosures. Appx. 409 (89 Fed. Reg. 33013). As explained in Defendants' opening brief, the Privacy Rule requires covered entities to make assessments involving "applicable law" to determine the authority of a "personal representative," 45 C.F.R. § 164.502(g), providing information about a deceased patient, *id*. § 164.512(g), and disclosing information relevant to a serious health threat, *id.* § 164.512(j). *See* Defs.' Br. in Supp. of Mot. Dismiss, Dkt. No. 40 (hereinafter "Defs. Br.") at 29. Plaintiffs have put forward no evidence to substantiate their assertion that determinations required by the Rule are "not within the scope of a healthcare provider's usual competence," or explained why covered entities can comply with pre-existing determinations but cannot ascertain the validity of the government's request for PHI. *See* Pls. Br. at 37–39.

Nor does the Rule require covered entities to "ignore what they do know" about state law. Pls. Br. at 38. The Department was clear that "if a person obtains reproductive health care that was unlawful," then the Rule's "prohibition does not apply" and the PHI may be disclosed consistent with the Privacy Rule. Appx. 408–09 (89 Fed. Reg. 33012–13); *see* C.F.R. § 164.502(a)(5)(iii)(B). The Rule's prohibitions would therefore be inapplicable if a covered entity has actual knowledge or a substantial factual basis to conclude that the care provided by someone else violates state law. *See* Appx. 408 (89 Fed. Reg. 33012). Neither is it unreasonable, let alone a "clear error of judgment," *Overton Park*, 401 U.S. at 416, to require covered entities to determine whether the reproductive health care they provide is "protected, required, or authorized by Federal law," 45 C.F.R. § 164.502(a)(5)(iii)(B)(2), when they presumably must already determine the legality of the care that they provide under federal law in their usual course of professional practice or can rely on the presumption of lawfulness when the care was provided by another entity.

IV. ANY REMEDIES SHOULD BE LIMITED TO PLAINTIFFS AND COMPLY WITH HIPAA'S SEVERABILITY PROVISION

For the reasons stated, this Court should deny Plaintiffs' motion in its entirety and enter

judgment for the Defendants. But if the Court enters judgment for Plaintiffs, the Court should limit any relief to the Plaintiffs. Any further relief would contravene equitable principles and defy the Department's clear intention of severability.

Under Article III, "a plaintiff's remedy must be 'limited to the inadequacy that produced [his] injury in fact.'" *Gill v. Whitford*, 585 U.S. 48, 66 (2018) (quoting *Lewis v. Casey*, 518 U.S. 343, 357 (1996)); *see also United States v. Nat'l Treasury Emps. Union*, 513 U.S. 454, 477–78 (1995) ("[W]e neither want nor need to provide relief to nonparties when a narrower remedy will fully protect the litigants."); *see also Texas v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 700 F. Supp. 3d 556, 572 (S.D. Tex. 2023).

Plaintiffs here are Dr. Purl and her private practice, which employs only three additional clinicians; this Court could award complete relief by enjoining the 2024 Rule with respect to them alone. *See id.* That injunction would fully remedy Plaintiffs' asserted injuries by permanently barring Defendants from enforcing the 2024 Rule against Plaintiffs. *See id.* ("'Equitable remedies, like remedies in general, are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit.'") (citation omitted); *California v. Texas*, 593 U.S. 659, 672 (2021) (valid Article III remedies generally "'operate with respect to specific parties'" rather than in the abstract) (citation omitted); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."); *Texas v. United States*, 126 F.4th 392, 420 (5th Cir. 2025) ("Remedies must be 'tailored to redress' a plaintiff's injury . . . and equitable remedies . . . should not provide more relief than 'necessary to give the prevailing party the relief to which [it] is entitled'") (citations omitted).

Plaintiffs offer a perfunctory argument for the vacatur and nationwide injunction of the 2024 Rule. Regardless of whether courts may vacate or enjoin agency action universally, they "should

'think twice—and perhaps twice again—before granting' such sweeping relief." *United States v. Texas*, 599 U.S. 670, 702 (2023) (Gorsuch, J., concurring) (citation omitted). Whether vacatur is appropriate turns on "the seriousness of the deficiencies of the action" and "the disruptive consequences of vacatur." *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021).

Universal vacatur in a challenge brought by one provider and her affiliated private practice would also have deeply disruptive consequences and cause nationwide harms to all of the other regulated parties, as well as the public's interest in the privacy of sensitive medical information. As set forth in Defendants' Brief, disclosures of such information would "irreparably harm relationships and reputations"; "result in the job loss or other negative consequences in the work place"; "deter[] [individuals] from seeking needed health care if they do not trust that their sensitive information will be kept private"; and withhold probative information from providers "necessary . . . for an appropriate treatment plan." Defs. Br. at 37–38 (quoting 89 Fed. Reg. 32990–91, 32984, 33057); *see also* Proposed Intervenor-Defs.' Br. in Supp. of Mot. Intervene, Dkt. No. 50 at 14–15. The Court should deny Plaintiffs' blanket request. *See Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) (plurality opinion) (remanding and opining that the district court could consider on remand "a more limited remedy" than universal vacatur, and should "determine what remedy . . . is appropriate to effectuate" the judgment); *Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur).

Any remedy the Court orders should also account for the unambiguous severability provision contained in HIPAA's implementing regulations, which directs that "[i]f any provision . . . is held to be invalid or unenforceable . . . as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law." 45 C.F.R. § 164.535. Whether a regulation is severable depends upon (1) "the intent of the agency" and (2) "whether the remainder

of the regulation could function sensibly without the stricken provision." *Texas v. United States*, 126 F.4th at 419 (cleaned up). Courts "'adhere to the text of a severability clause in the absence of extraordinary circumstances.'" *Id.* (citation omitted).

The 2024 Rule meets both prongs. The Rule unequivocally provides that the Department "intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly." Appx. 444 (89 Fed. Reg. 33048). And the severability provision explicitly contemplates injunctions as to "persons" and "plaintiffs," indicating that any injunctive relief should apply only to the plaintiffs before the Court. 45 C.F.R. § 164.535. As explained in the 2024 Rule and Defendants' opening brief, the Court could simply enjoin the Department from enforcing the Rule with respect to legitimate reports of child abuse to the extent the Court concludes that the 2024 Rule limits the ability to report child abuse, or the Court can sever definitions of certain terms from the remainder of the Rule's provisions if it finds they are improper. *See* Appx. 444 (89 Fed. Reg. at 33048) (explaining that, for example, if "the definition of 'public health'. . .is held to be invalid and unenforceable, the other modifications to the rules shall remain in full force and effect to the extent that they are not directly related to the definition of public health"); Defs. Br. at 39. Plaintiffs' failure to address the Rule's express severability provision is fatal to their request to vacate or enjoin "the entire 2024 Rule," and none of the cases they cite implicate severability provisions. Pls. Br. at 39–41; *see Texas*, 126 F.4th at 420 ("Because [the agency] intended the aspects of [the rule] to be severable and to function independently from one another, the district court erred by not severing the [] provisions"). Plaintiffs' *ipse dixit* that the Rule is a singular "illegal effort" utterly fails to address the Department's intent or Rule's functionality once severed. Pls. Br. at 40. Any relief ordered should not transgress the Department's clear intention of severability, which would imperil protections that are vital to

safeguard Americans' sensitive medical information.

CONCLUSION

For the forgoing reasons, the Court should deny Plaintiffs' motion for summary judgement.

* * *

Date: March 3, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Shannon R. Selden
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